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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,836,965

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,836,965, which claims the medical device S8 Over-the-Wire System, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 413 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent Nos. 5,292,331; 5,800,509; 5,879,382; 5,891,190; 6,159,229; 6,309,402 and 6,344,053 based on the regulatory review period of PMA P030009 for the medical device, S8 Over-the-Wire System.

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant expressly elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the applications for patent term extension in the above identified patent number and U.S. Patent Nos. 5,800,509; 5,879,382; 5,891,190; 6,159,229; 6,309,402 and 6,344,053 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. (Absent an express election, a certificate of extension will be issued in U.S. Patent No. 5,292,331). In the absence of a request for reconsideration, and if U.S. Patent No. 5,836,965 is elected, the Commissioner will issue to the patentee a certificate of extension, under seal, for a period of 413 days in U.S. Patent No. 5,836,965.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 23, 2007 (72 Fed. Reg. 8182). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} \text{ (477 days) + 175 days} \\ &= 413 \text{ days (1.1 years)}\end{aligned}$$

Since the regulatory review period began December 20, 2001, after the patent issued (November 17, 1998), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,836,965
Granted:	November 17, 1998
Original Expiration Date ¹ :	November 17, 2015
Applicant:	Brad Jendersee, et al.
Owner of Record:	Medtronic Vascular
Title:	Stent Delivery and Deployment Method
Product Trade Name:	S8 Over-the-Wire System
Term Extended:	413 days
Expiration Date of Extension:	January 3, 2017

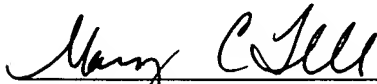
¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
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Rockville, MD 20857

RE: S8 Over-the-Wire System
FDA Docket No.: 2004E-0306

Attention: Beverly Friedman